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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,637	11/25/1997	ELAZAR RABBANI	ENZ-53(DIV5)	4643

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/978,637	RABBANI ET AL.	
	Examiner	Art Unit	
	J. D. Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *318-323* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *245,248-256,260,262,264,265,268,270,272,284,286-290,296-299,303-313 and 317* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 245,248-256,260,262,264,265,268,270,272,284,286-290,296-299,303-313 and 317-323.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 April 2005 has been entered.

Status of Application/Amendment/Claims

Applicant's responses filed 28 April 2005, and 15 November 2004 have been considered. Rejections and/or objections not reiterated from the previous office action mailed 11 February 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Answer to Arguments, Restriction/Election

In applicants response dated 28 April 2005, it was asserted that claims 318 and 323, which are newly added claims filed with the amendment of 6 November 2003 and subsequently withdrawn by original presentation, should properly be considered linking claims. Applicants assert that claims 318 and 321 constitute linking claims because each of these claims links the

products recited in claims 245 and 299 with processes of using this product, as recited in claims 318 and 321. Applicants reasoning is based on a passage from MPEP § 809.03, which defines linking claims as comprising claims directed to inventions which are normally divisible, yet are inseparable due to the presence of a linking claim, and which further provides specific examples of what are properly considered linking claims.

However, it is not clear from applicants arguments which of the specific examples is being relied upon to support their argument that such claims are linking claims, because applicants have not pointed to which example is supportive, and neither is it clear by looking at the examples which of said examples would be supportive. Of the examples, example A) is directed to genus species situations, which is not applicable instantly. Examples B) and D) both recite processes of making, and are thus considered inapplicable instantly. Only step C) recites a means for practicing a process which links proper apparatus and process claims. However, the instant claims are not directed to "means", neither is an apparatus recited. Finally, as pointed out in the action mailed 11 February 2004, a product and a process of using the product can be. shown to be distinct if the product is claim can be used in a materially different process. In the instant case the product can be used in a materially different process of using the product nucleic acid constructs of claims 245 and 299. For example, said products can be used to cleave targets in a cell free assay to determine binding and cleavage rates. Accordingly, claims 318-323 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Finally, Applicant's attention is directed to the following recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

The requirement is still deemed proper and is therefore made FINAL.

Claim rejections – 35 USC § 112

Claims 265, 268, 270, 272, 284, 286-290, 296-299, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Claim 265 is drawn to a nucleic acid which, when present in a cell, produces a gene product from an snRNA promoter, wherein the gene product comprises a nuclear localization sequence comprising a portion of snRNA, wherein the portion comprises at least two stem loops present at the 3' end of native snRNA, and a reimportation signal, and an antisense or sense nucleic acid. Dependent claim 270 recites the nuclear localized sequence of claim 265, comprising a portion of U1 snRNA comprising C and D loops. Claims 268, 272, 284, 286-290, and 296-298 are rejected for being dependent on claim 265. The invention of Claim 299 is drawn to a nucleic acid which produces more than one specific nucleic acid which are complementary to a specific portion of one or more mRNA targets in the cell.

The specification as originally filed is not considered to support the language of claim 265 drawn to producing a gene "from an snRNA promoter", or the language drawn to "a portion of snRNA which comprises at least two stem loops present at the 3' end of native snRNA". This is because no teaching of an snRNA promoter in the context of the present invention is apparent in the specification and one of skill would not divine its presence in the lack of such a teaching. It follows that any reference to a 3' stem loop structure of the snRNA is also lacking. While the specification does teach a reference to snRNA, the reference to snRNA as recited in the original claims and specification as filed is contemplated as a potential nucleic acid "sequence of interest" and not as a localizing entity, as now instantly recited [see originally filed claim 265, which recites a compound comprising 1) a portion of a *localizing entity* and 2) a nucleic acid *sequence of interest*]. In contrast, the instant claims now recite the snRNA entities as part of a localizing entity, rather than the sequence of interest as originally disclosed. Thus the context in which the snRNA now appears is what necessitates its rejection as constituting new matter.

In fact, the instant claim refers to the snRNA as not only a localizing entity, which is considered new matter for reasons described above, but now additionally refers to the snRNA as a "*nuclear* localization" sequence. The only apparent reference to a "*nuclear* localization" sequence appears in originally filed claim 269, and specifies that the nuclear localization sequence must be a sequence of interest, and not a localizing entity. Therefore, the use of a nuclear localization sequence as a localizing entity is also considered to comprise new matter, since it was heretofore apparently contemplated only as a "sequence of interest".

Similarly, there is no apparent reference in the specification as filed to a reimportation signal, nor to C or D loops of U1 snRNA. One skilled in the art with therefore not consider reimportation signals nor C or D loops as part of the originally contemplated invention, and references thereto are considered new matter.

Finally, claimed 299 recites compounds that produce sequences that bind to specific portions of one or more mRNA or protein targets. A review of the specification has not revealed where support for the recitation of one *or more* targets exists. One of skill in the art would not have viewed the teachings of the specification drawn to the use of molecules complementary to a single target and considered such molecules drawn to *more than one* target to be a part of the instant invention, and references thereto are considered to constitute new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 272 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 272 recites the composition of claim 265 that is single-stranded. However claim 265 requires at least two stem loops in the structure. Because stem loop structures are necessarily double stranded, the requirement of claim 272 for single-strandedness cannot be met. The metes and bounds of this claim are therefore unclear.

Claims 303-313 recite "the nucleic acid of claim 299". However, claim 299 recites a nucleic acid that itself produces more than one nucleic acid. It is not clear which nucleic acid is being referred to.

Claim 307 is missing a period. It is unclear therefore, whether this claim constitutes a single sentence or encompasses more, making the metes and bounds unclear.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 245, 248-256, 260, 262, 264, 265, 268, 270, 272, 284, 286-290, 296-299, 303-313 and 317 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The invention of the above listed claims 245, 248-256, 260, 262, 264 is drawn to composition comprising, *inter alia*, a primary nucleic acid which synthesizes a secondary nucleic acid which synthesizes a gene product, wherein the primary nucleic acid is single or double

stranded, or is made of DNA RNA or nucleic acid analogues, or wherein said DNA, or said RNA, are modified, or wherein said composition comprises a signal processing sequence, which may be a promoter, an initiator, a terminator, an intron, a cellular localization element, or a combination of the foregoing, or wherein the gene product is single-stranded, or is sense or antisense, and to eukaryotic cells thereof.

The above recited invention is nonstatutory for the following two reasons. First, the composition is considered to be a product of nature, because it is not claimed as being in an isolated state. Second, the composition reads on a human being. A human being is a composition which comprises DNA which is a primary nucleic acid, which makes RNA which comprises a secondary nucleic acid, which lead to the production of proteins, which comprise gene products. The primary nucleic acids comprise signal processing sequences which are promoters, initiators, etc. and which makes sense nucleic acid strands. Accordingly, the claims are rejected for being drawn to nonstatutory subject matter.

The invention of claims 265, 268, 270, 272, 284, 286-290, and 296-298 are drawn to a composition of matter comprising a nucleic acid comprising an snRNA nuclear localization sequence operatively linked to sense or antisense nucleic acids. Claims depending therefrom specified the sense or antisense nucleic acids to consist of DNA or RNA or hybrids or chimeric thereof, or wherein the nuclear localized sequence comprises a portion of U1 RNA comprising C and D loops, or such compositions as introduced ask in vivo, or in vivo, or biological systems thereof, or processes for localizing said compositions in cells.

As above, the instant invention is considered nonstatutory for two reasons. First the composition is considered to be a product of nature, because it is not claimed as being in an

isolated state. Second, the composition reads on a human being. A human being is a composition comprising a nucleic acid comprising an snRNA nuclear localization sequence which is operatively linked to sense nucleic acids, wherein the snRNA nuclear localization sequence is a you one sequence. The claimed process of localizing such compositions occurs during normal mitotic cell division which causes chromosomes to be introduced into new cells via natural processes. Accordingly, the invention of the above claims is considered to be drawn to naturally occurring processes which are nonstatutory.

The invention of claims 299, 303- 313, and 317 are drawn to nucleic acids which, *inter alia*, produce more than one specific nucleic acid which are complementary to specific portions of mRNA targets wherein the nucleic acids are RNA, DNA, or analogues thereof, or are modified, or such nucleic acids comprising more than one promoter or more than one initiator or both, or such nucleic acids produced independently from different promoters, or different initiators, or such nucleic acids that are complementary to viral or cellular RNA, or to means of delivery thereof.

Claim Rejections - 35 USC § 112

Claims 245, 248-256, 260, 262, and 264 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above claims is drawn to compositions comprising "a primary nucleic acid, which upon introduction into a eukaryotic cell synthesizes a secondary nucleic acid which synthesizes a gene product, or a tertiary nucleic acid, or both, in said eukaryotic cell..."

The specification is not considered to provide adequate support for nucleic acids which synthesize other nucleic acids. It is well known in the nucleic acid arts that nucleic acid synthesis is propagated by protein polymerases, and not by nucleic acids. While a primary nucleic acid may form a template for the synthesis of a secondary nucleic acid, this is not what is directly suggested by claim language which recites a primary nucleic acid which synthesizes a secondary nucleic acid. The latter phrase would require a primary nucleic acid that it self synthesizes a secondary nucleic acid. The specification simply does not describe this. While the prior art to discloses a small subset of enzymatic nucleic acids that are capable of aminoacylation, and are thus capable of forming you the building blocks required in polypeptide synthesis, the examiner is unaware of any teachings of an enzymatic nucleic acid capable of ligating nucleic acids to form a polynucleotide. Regardless, such ligation-capable nucleic acids which synthesize other nucleic acids are neither taught nor suggested in the instant specification. Accordingly, reference to primary nucleic acids which synthesize secondary nucleic acids are not considered to be supported by the teachings of the instant specification and prior art, and therefore lack written description.

In response to arguments submitted by applicants insofar as they might apply to this new grounds of rejection, Applicants continue to refer to an alleged requirement made in the Official action mailed 1 may 2003, whereby the previous examiner allegedly required recitation of a specific chemical structure in order to satisfy the written description requirement. Applicants

have pointed to page 15 of said action in asserting that such a requirement was made. Page 15 has been reproduced as follows:

> "[...]teach the direct correlation between any such vector constructs (including the Ul-anti-HIV constructs) as having a specific function in a cell in a whole organism.
>
> Response to Arguments
>
> Applicant's arguments filed June 19, 2002, have been fully considered but they are not persuasive. Applicants 'assert that adequate description has been provided. A detailed description of the constructs for producing products in accordance with the present invention is described in the present specification and includes working examples and figures.... Sufficient identifying characteristics of the constructs, compositions and kits of the present invention is provided as noted above in the specification. Additionally, a sufficient number of species have been disclosed. Moreover, the terminology employed by Applicants to describe their constructs (page 169) is accepted in the art, and as such, should be deemed to satisfy the written description test under the law.'
>
> In response, although actual reduction to practice is not required to adequately describe the claimed invention, one of skill in the art must be able to readily envisage both the breath of the genus of claimed constructs as well as the representative number of species of any such genus of constructs as defined by certain common attributes and features. In the instant case, the constructs are nucleic acid constructs which when present in a cell produce a product as well as other possible products. This genus claimed embraces the production of a product in any cell."

Contrary to applicant's position, the examiner clearly stated that actual reduction to practice is *not* required. Although it was stated that one of skill must be readily able to envisage the breadth of the genus of claimed constructs, this statement is considered sound in view of established case law. Thus, no requirement is currently being made, nor has ever been made, for the recitation of a specific chemical structure in order to satisfy the written description requirement, however helpful such specificity would be in establishing written description.

Applicants have submitted a declaration under 37 CFR 1.132. Since these arguments appear more directed to the rejection made under enablement, comments and said declaration are addressed under the enablement rejection.

Claims 290 and 296-298 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of selectively expressing a nucleic acid product

in a cell in cell culture (*in vitro*), does not reasonably provide enablement for methods of expressing the nucleic acids in a whole organism (*in vivo*). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants traverse the instant rejection by taking issue with the examiner's assertion that none of the references previously supplied by applicants in alleged support of enablement actually show in vivo inhibition "Specifically, two references, Vlassov et al., 1993, shows penetration of oligonucleotides into mice; Agarwal [sic] shows the metabolism of phosphorothioates in vivo.". This argument is not convincing, because it does not allege that these references show in vivo inhibition. While Vlassov is alleged to show penetration, applicants have not alleged that Vlassov shows inhibition. Similarly, Agrawal is alleged to show metabolism, but not inhibition. It is precisely the inhibition that is at issue here, since it is such inhibition that is considered unpredictable, and therefore forms the basis for the instant rejection for lacking and enablement. Furthermore, applicants arguments that all references submitted in exhibit D should be considered "to show the utility of the claimed compositions, and in response to the rejections of the utility of antisense sequences. Applicants argue that this is permissible. However, there was no utility rejection in any previous action. It is granted to the instant compositions have utility, that is the utility of inhibiting their target. The issue of enablement is a different rejection, and is based on the predictability of the claimed invention, and whether or not undue experimentation is required to practice the invention as claimed. Arguments drawn to post filing references and utility are not considered indicative of the predictability of the invention as of the filing date of the instant application.

Applicants have submitted a declaration under 37 CFR 1.132. Said declaration asserts that a construct containing a U1/anti-HIV sequence is stable he incorporated into three patients cells for at least 48 months. The declarant indicates that constructs comprising antisense sequences directed to the TAR region and against two separate sites of the TAT region were inserted into three U1 genes. The declarant indicates that these constructs were made in NIH 3T3 cells using plasmids containing the MMLV gag-pol region, Gibbon ape leukemia virus env region and the coding sequence for the HTLV-II. The declarant indicates that these constructs were transfected into the peripheral blood mononuclear cells of patients following a four-day administration of granulocyte colony stimulating factor, whereupon the cells were reinjected into said patients. Patients were monitored over time for the expression of the antisense RNA, which was detected in all five patients tested at six to nine months.

The declaration summarized above is considered convincing, but not over the full scope of the claimed invention. The claimed invention is directed to the use of vectors comprising the use of U1 snRNA promoters to drive expression of an antisense or sense nucleic acids whereupon said vectors are introduced into cells. The declaration describes the use of such constructs, but in contrast to breadth of the claimed invention, which encompasses in vivo use, the declaration describes the ex vivo treatment of cells followed by reintroduction into the patient. Since the ex in vivo administration is done outside the patient, and essentially amounts to an in vitro treatment, it is not considered representative of the in vivo introduction of such constructs for the purpose of treatment. This distinction lies at the heart of this rejection, since it has been granted that applicants are considered to be enabled for the use of nucleic acid

constructs in vitro. It is the claimed breadth encompassing in vivo use that is not considered to be enabled, and the rejection is maintained accordingly.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 245, 248-256, 260, 262, 264, and 317 are rejected under 35 U.S.C. 102(b) as being anticipated by Bebenek et al. (J. Biol. Chem. 1989. 264(28)16948-16956).

The claims of the instant invention are drawn to a composition comprising a primary nucleic acid which synthesizes a secondary nucleic acid which synthesizes a gene product or a tertiary nucleic acid or both wherein said primary nucleic acid is not obtained with said secondary or tertiary nucleic acid or said gene product. The composition may be single or double stranded, or said primary nucleic acid may consist of DNA, RNA, and nucleic acid analogues, or combinations thereof, or wherein said DNA or RNA or both are modified, or wherein said tertiary nucleic acid is selected from the group consisting of DNA, RNA, a DNA-RNA hybrid, a DNA-RNA chimera and a combination of the foregoing, or said composition further comprising a signal processing sequence, wherein said signal processing sequence may be a promoter, and initiator, a terminator, and intron, a cellular localization element, and a combination of the foregoing, or wherein said signal processing sequence is in any of the primary, secondary, or tertiary nucleic acids, or wherein said gene product is single-stranded, or wherein said gene

product is a sense or antisense nucleic acid, or to cells thereof. The invention is also drawn to compositions wherein the secondary nucleic acid is DNA and the tertiary nucleic acid is RNA.

Although the phrase "synthesizes" is considered to be unsupported by the teachings of the instant specification, as outlined above in the rejection under 35 U.S.C. § 112 first paragraph written description, for the purposes of searching the prior art, the term "synthesizes" is considered to refer to nucleic acids which encode and provide a transcription template for other nucleic acids.

Bebenek et al. teaches a process of HIV replication whereby the final product is mutated from the original product. Therefore, Bebenek et al. teaches a composition comprising a primary nucleic acid (i.e. HIV infectious strand) which synthesizes a secondary nucleic acid (a double stranded DNA) which synthesizes a tertiary nucleic acid (a mutated HIV infection strand), wherein said primary nucleic acid is not obtained with said secondary or tertiary nucleic acid due to its mutation. The primary nucleic acid is single stranded, and consists of DNA and is modified. Said tertiary nucleic acid is DNA and comprises a signal processing sequence, consisting of a promoter, and wherein said gene product is a sense nucleic acid.

Claims 245, 248, 249, 251-255, 260, 262, and 264, are rejected under 35 U.S.C. 102(b) as being anticipated by Panayotatos et al. (U. S. Patent Number 4,716,112).

The claims of the instant invention are drawn to a composition comprising a primary nucleic acid which synthesizes a secondary nucleic acid which synthesizes a gene product or a tertiary nucleic acid or both wherein said primary nucleic acid is not obtained with said secondary or tertiary nucleic acid or said gene product. The composition may be single or double

stranded, or said primary nucleic acid may consist of DNA, RNA, and nucleic acid analogues, or combinations thereof, or wherein said DNA or RNA or both are modified, or wherein said tertiary nucleic acid is selected from the group consisting of DNA, RNA, a DNA-RNA hybrid, a DNA-RNA chimera and a combination of the foregoing, or said composition further comprising a signal processing sequence, wherein said signal processing sequence may be a promoter, and initiator, a terminator, and intron, a cellular localization element, and a combination of the foregoing, or wherein said signal processing sequence is in any of the primary, secondary, or tertiary nucleic acids, or wherein said gene product is single-stranded, or wherein said gene product is a sense or antisense nucleic acid, or to cells thereof.

Panayotatos teaches a composition comprising a primary nucleic acid (a vector) which synthesizes a secondary nucleic acid (mRNA) which synthesizes a gene product (a polypeptide) wherein said primary nucleic acid is not obtained with said secondary or tertiary nucleic acid or said gene product. The composition is double stranded and said primary nucleic acid consists of DNA, said tertiary nucleic acid is DNA, said composition comprises a signal processing sequence, wherein said signal processing sequence is a promoter, and said gene product is single-stranded. Panayatos also teaches cells thereof.

Claims 265, 268, 270, 272, 284, and 286-298 are rejected under 35 U.S.C. 102(b) as being anticipated by Neuman de Vegvar (Nucl. Acids Res. 1989. 17(22)9305-9318).

The claims are drawn to a nucleic acid composition capable of producing a gene product from an snRNA promoter, wherein the gene product comprises a nuclear localization sequence comprising a portion of snRNA, wherein said portion of snRNA further comprises sequences for

at least two stem loops present at the 3' end of native snRNA, and reimportation signal, and an antisense or sense nucleic acid. The sense or antisense nucleic acid of said composition may comprise DNA, RNA, a DNA-RNA hybrid, a DNA-RNA chimera, or a combination of the foregoing. The composition may also comprise U1 RNA which further comprise C and D loops,or may be single-stranded. The invention is also drawn to cells, biological systems, and processes of using thereof.

Newman de Vegvar teaches a nucleic acid composition capable of producing a gene product from an snRNA promoter, wherein the gene product comprises a nuclear localization sequence comprising a portion of snRNA, wherein said portion of snRNA further comprises sequences for at least two stem loops present at the 3' end of native snRNA, which is a reimportation signal, and a sense nucleic acid. The sense or antisense nucleic acid of said composition comprises DNA, and U1 RNA which further comprise C and D loops, and is single-stranded. Newman the Vegvar also teaches cells, biological systems, and processes of using thereof (see 1st line of materials and methods for example).

Claims 299 and 303, 304, and 307-313 are rejected under 35 U.S.C. 102(b) as being anticipated by Junker et al. (Antisense Res Dev. 1994 Fall;4(3):165-72.).

The invention of the above claims is drawn to a nucleic acid which produces more than one specific nucleic acid which are nonhomologous with each other and are complementary to a specific portion of an RNA target or which binds a specific protein. Said nucleic acid may comprise DNA, RNA, nucleic acid analogues, or combinations thereof. The DNA or RNA may be modified, or the nucleic acid may comprise more than one promoter were one initiator or

both. The nucleic acid may comprise a different promoter or initiator for each specific nucleic acid, or these specific nucleic acid sequences maybe complementary to a viral or cellular RNA or bind to a viral or cellular protein, or a combination of the foregoing. The specific nucleic acid sequence may act as antisense. The cellular protein may comprise a localizing protein or a decoy protein. The localizing protein may comprise a nuclear localizing protein or a cytoplasmic localizing protein. The decoy protein may bind a protein required for viral assembly or viral replication. The specific nucleic acid may comprise antisense RNA, antisense DNA, a protein binding nucleic acid sequence, or a combination of the foregoing. The invention also comprises a means of delivering said nucleic acids to a cell.

Junker et al. discloses the use of a vector comprising sequences encoding two different antisense oligos targeted to HIV. Thus, Junker et al. teaches a nucleic acid which produces more than one specific nucleic acid which are nonhomologous with each other and are complementary to a specific portion of an RNA target. Said nucleic acid comprises DNA, which is modified RNA. Junker teaches that these specific nucleic acid sequences are complementary to a viral target, and acts as antisense RNA. Junker also teaches a means of delivering said nucleic acids to a cell.

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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